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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,771

08/25/2006

Michael S. Kinch

10271-131-999

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20583

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06/05/2009

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

06/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,771	Applicant(s) KINCH, MICHAEL S.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/13/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,11-22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,11-22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 1-3, 6, 11-22 and 24 are pending.
Claims 1, 6, 12 and 24 have been amended.
Claims 4, 5, 7-10 and 23 have been cancelled.
Claims 1-3, 6, 11-22 and 24 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-3, 6, 11-22 and 24 under 35 U.S.C. 102(e) as being anticipated by Kiener et al./ WO 2005/000207 A2 (effective filing date May 30, 2003/ IDS reference B06 submitted August 25, 2006) is withdrawn in light of Applicant's filing of a declaration under 35 U.S.C. § 1.132 of Michael S. Kinch on March 13, 2009 declaring Mr. Kinch is the sole inventor. Claims 4, 5, 7-10 and 23 have been cancelled.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-3, 6, 11-22 and 24 under 35 U.S.C. 103(a) as being unpatentable over Sun et al./ WO 2004/045544 A2 (effective filing date 19 November 2002), and further in view of Kiener et al./ WO 2005/000207 A2 (effective filing date May 30, 2003/ IDS reference B06 submitted August 25, 2006) is withdrawn in light of the Kiener reference is not available as prior art. Claims 4, 5, 7-10 and 23 have been cancelled.

5. The rejection of claims 1-3, 6, 11-22 and 24 under 35 U.S.C. 103(a) as being unpatentable over Serrero/ U.S. Patent Application Publication number 2003/0108950 A1 (filed October 28, 2002/ IDS reference A10 submitted August 25, 2006), and further in view of Kiener et al./ WO 2005/000207 A2 (effective filing date May 30, 2003/ IDS reference B06 submitted August 25, 2006) is withdrawn in light of the Kiener reference is not available as prior art. Claims 4, 5, 7-10 and 23 have been cancelled.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

6. The rejection of claims 1-3, 6, 11-22 and 24 under 35 U.S.C. 102(e) as being anticipated by Sun et al./ WO 2004/045544 A2 (effective filing date 19 November 2002) is maintained and made. Claims 4, 5, 7-10 and 23 have been cancelled.

Applicants sets forth the criteria mandated by 35 USC § 102 and notes "Sun does not teach or suggest a method of diagnosing a pre-cancerous condition", see Remarks submitted March 13, 2009, last sentence of page 5. Applicants assert the language used by Sun limits the reference from being used as prior art and does not read on the diagnosis of a pre-cancerous condition, see Remarks, page 6. Applicants' arguments and points of view have been carefully considered, but found unpersuasive.

Applicants' claims comprising two active steps, a) contacting cells from a subject with a PCDGF antibody and b) detecting said antibody and antibody binding, wherein higher level detection of PCDGF antibody than level of PCDGF binding in the sample of a control subject. The use of the terms "tumorigenic cell" and "cancer cells" does not preclude the prior art from reading on the claims. Sun clearly meets these two limitations and moreover, as the claims are written the detecting of increased PCDGF binding clearly denotes a pre-cancerous condition. Sun discloses on page 16 of the document,

[0043] Anti-PCDGF receptor antibodies are capable of binding to tumorigenic cells but not to normal cells. As shown in FIG. 7, anti-PCDGF receptor antibodies bind strongly to breast cancer tissue (panels B and C) but not to normal tissue (panel A) in an immunostaining protocol using 10 micrograms/ml of 6G8 anti-PCDGF receptor antibody. Thus, anti-PCDGF receptor antibodies can also be used to diagnose tumorigenicity by comparing the level of PCDGF receptor in a tissue sample or biopsy to the level of PCDGF receptor in normal tissue. Elevated levels of PCDGF receptor indicate the cells are tumorigenic.

The claimed invention is also disclosed in claims 38-47. The said antibody, including humanized antibodies contact tumorigenic cells such as cells derived from blood, urine, nipple aspirate, prostate, neural and lung via immunoassays, see page 7, section 0024; page 12, section 0034; page 13, section 0035; and page 16, section 0044.

7. The rejection of claims 1-3, 6, 12 and 24 under 35 U.S.C. 102(e) as being anticipated by Serrero/ U.S. Patent Application Publication number 2003/0108950 A1 (filed October 28, 2002/ IDS reference A10 submitted August 25, 2006) is maintained and made. Claims 4, 5, 7-10 and 23 have been cancelled.

Applicants' assert "Serrero does not teach a method of diagnosing a pre-cancerous condition" and reiterate the criteria mandated by 35 USC § 102, see Remarks, page 7. Applicants' arguments and points of view have been carefully considered, but found unpersuasive.

Applicants' claims comprising two active steps, a) contacting cells from a subject with a PCDGF antibody and b) detecting said antibody and antibody binding, wherein

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higher level detection of PCDGF antibody than level of PCDGF binding in the sample of a control subject. Serrero clearly meets these two limitations and moreover, as the claims are written the detecting of increased PCDGF binding clearly denotes a pre-cancerous condition. GP88 is art known to as 88 kDa glycoprotein PC cell-derived growth factor (PCDGF/GP88), also known as progranulin. The publication number discloses measuring the concentration of GP88 in blood, plasma, serum, saliva, urine, needle biopsies from breast cancer patients, as well as other biological fluids detected by immunoassay methods including the use of antibodies, hence reading on Applicants' claims, see abstract; page 8, section 0099-page 9, section 0106.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.

01 June 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643